

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested.

By the present amendment, claims 22, 53-54, 63-64, 66-67, 85, 87-88, 91-92, 94-95, 100, 102-103, 106, 107-108 under examination have been amended. Corresponding amendments have been made to claims 1-2, 43-44, 70-71, 81-82 98-99 and 104-105, which remain withdrawn from consideration pending rejoinder.

In particular, the independent claims 1-2, 22, 63-64, 70-71, 85, 91- 92, 98-99, 100, 102-103, 104-105, 106 and 107-108 have been amended to recite a length of “at least 20 consecutive nucleotides” of the nucleotide sequence of the nucleic acid of interest. By this amendment claims 43, 53, 66, 81, 87 and 94 became redundant, and were consequently amended to recite “at least 50 consecutive nucleotides, and claims 44, 54, 67, 82, 88 and 95 were amended to recite “at least 100 consecutive nucleotides.” Claim 46 has been amended in its dependency only.

Furthermore, for consistency of terminology, and to avoid any potential ambiguities, the phrase “intron sequence” has been replaced by “intron” wherever it appeared in the claims.

Support for recitation of at least 20, 50 and 100 consecutive nucleotides can be found at least on page 21, lines 5-30 and support for “intron” can be found in the specification at least on page 23, line 6.

New dependent claims 109-134 have been added. These claims mirror language of claims already on record. In particular, the additional features of new claims 109, 110, 111, 115, 119, 123, 127 and 131 correspond to the features recited in previously presented claims

3 and 72. The features recited in new claims 112, 116, 120, 124, 128 and 132 correspond to recitations in previously presented claims 40, 42, 65, 80, 86 or 93. The features recited in new claims 113, 117, 121, 125, 129 and 133 correspond to recitations in previously presented claims 43, 53, 66, 81, 87 or 94. The features recited in new claims 114, 118, 122, 126, 130 and 134 correspond to features recited in previously presented claims 46, 56, 68, 83, 89 or 96. Of these newly added claims, claims 111-114 and 123-127 are method claims and are accordingly expected to be withdrawn from consideration pending the rejoinder of all method claims.

No prohibited new matter has been introduced by way of the above amendments. Applicants reserve the right to file a continuation or divisional application on any subject matter that may have been canceled by way of this amendment.

Updated Priority Information

By the present amendment, the cross-reference to the priority applications that was inserted before the first line of the specification by preliminary amendment has been updated to reflect the conversion of the priority applications from non-provisional to provisional status and the consequent assignment of serial numbers in the 60 series. Applicants note that PAIR correctly reflects the serial numbers of the converted priority applications.

Pending Petition To Correct Inventorship

The Examiner is respectfully reminded that a Petition to Correct Inventorship was filed in this application on September 13, 2006 and that further supporting documentation in the form of a copy of a Declaration pursuant to 37 C.F.R. § 1.63 without handwritten

corrections was filed on December 1, 2006. An indication that the petition has been granted is respectfully requested.

Interview Summary

Applicants thank the Examiner for the courtesy of a personal interview on November 30, 2007. The Examiner assisted Applicants in understanding the basis for the rejections in the present Office Action. Applicants believe that the present amendments and the below remarks address the issues in the Office Action in accordance with that understanding. The prior art of record was discussed and applicants pointed out deficiencies in the cited art substantially as set forth below.

Maintained rejections under 35 U.S.C. §112, first paragraph.

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed February 8, 2007.

Applicants fully maintain the arguments presented in the response and declarations filed August 8, 2007. As further evidence applicants submit as Exhibit A, attached hereto, an additional declaration by Dr Peter Schofield supporting Applicants' position that the specification includes a written description of the claimed invention such that a person of ordinary skill in the art would have recognized that the inventors were in possession of the claimed invention at the time that the application was filed. Dr. Schofield's declaration provides further clear evidence that the term "intron" defined a well characterized genus of DNA elements possessing common structural and functional features.

The Examiner has alleged that the term “intron sequence” encompasses a broad range of highly variable sequences that do not necessarily require the limitations of conserved excision or splicing signals that Applicants have argued are implicit in the recitation of the terms in the claims. Applicants maintain that the claims as presented have required the presence of a functional intron with all the conserved structural elements implicit in that term where the claims recited either an intron or an intron sequence. However, for the sake of consistency, and to avoid any ambiguity on this point, the term “intron sequence” has been replaced by “intron” wherever it appeared in the claims. Applicants respectfully submit that the amendment to the claims to recite “intron” now particularly and distinctly includes the structural limitations that are inherent in an intron as would be well understood by a person of ordinary skill. The genus of intron included a large and representative number of well characterized members having well understood common structural and functional properties. A person skilled in the art clearly knows and would have known that what is defined by an “intron” includes the presence of consensus sequences at both ends of the intron for intron splicing. See, e.g. DECLARATION OF ELISABETH DENNIS at ¶ 13; DECLARATION OF PETER SCHOFIELD at ¶¶ 13 and 15.

The declarations that Applicants have provided are ample evidence that a person of ordinary skill in the art would have recognized the sufficiency of the present specification in regards to the recitation of intron in the claims such that a person of ordinary skill in the art would have recognized that the inventors were in possession of the claimed invention at the time that the application was filed.. Accordingly, withdrawal of the rejection is respectfully requested.

New rejections under 35 U.S.C. §102

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §102(b) as being anticipated by Flavell. To the extent the rejection might still be applied to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner alleges that Flavell teaches plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense sequence includes at least 10 consecutive nucleotides having 100% sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence. The Examiner particularly points to the abstract and text on pages 3490-3491.

The Flavell publication is a review article concerning the co-suppression phenomena in plants, and hypothetical models attempting to explain the mode of action in reducing gene expression. The models presented always involve the generation of antisense RNA based on the sense template introduced with a chimeric DNA, either by the action of RNA dependent RNA polymerase on the sense template to generate antisense RNA (FLAVELL, at 3492-93, bridging ¶¶). As an alternative it is suggested that the transcribed region encoding the sense RNA could be accidentally transcribed into antisense RNA from an active promoter in the opposite orientation on the inserted T-DNA (FLAVELL, 3494; 3rd column, end of the penultimate paragraph). Assuming this hypothesis to be correct, this could at best generate separate sense and antisense RNA molecules, but not an RNA region capable of forming an

artificial hairpin RNA structure comprising two annealing RNA sequences as currently claimed.

A hairpin RNA is defined in the current application as being a self-annealing double stranded RNA molecule, which in its simplest representation consists of a double stranded stem made up by the two annealing strands (one of which corresponds to at least part of the target nucleic acid of interest), connected by a single stranded RNA loop (paragraph spanning pages 14-15) As indicated in the application (page 22, lines 19 to 23) an artificial hairpin RNA is a non naturally occurring RNA molecule whereby sense and antisense are occurring simultaneously in one RNA molecule, preferably separated by a spacer region.

Furthermore, the Flavell publication is entirely silent on the presence of an intron, particularly an intron which is heterologous to the sense sequence, in the transcribed region of the chimeric genes recited in the claims. During the courteously granted interview of December 1, 2007, the Examiner pointed out that the term “intronic sequence” might be reasonably interpreted as reading on “any sequence”, and accordingly this feature would not further limit the scope of the claim. Such a construction is unreasonably broad in that it would deny any meaning to a claim term. All terms in a claim must be interpreted as having meaning. Nevertheless, the present amendment of the claims to read “intron” renders this extreme construction moot. As indicated in the declarations by Drs Dennis and Schofield, the person skilled in the art clearly knows what is defined by an “intron” including the presence of consensus sequences at both ends of the intron, important for intron splicing. DECLARATION OF ELISABETH DENNIS at paragraph 13; DECLARATION OF PETER SCHOFIELD at paragraphs 13 and 15. Particularly, these declarations make it clear that an “intron” cannot be equated with “any sequence.”

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Flavell does not describe every element of the claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §102(b) as being anticipated by Metzloff et al. To the extent the rejection might still be applied to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner alleges that Metzloff et al teach plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense sequence includes at least 10 consecutive nucleotides having 100% sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence. The Examiner particularly points to the figures 1 and 2 on page 846, Table 1 and text on pages 849-850, and figure 7 on page 852.

Metzloff et al. disclose a model to explain co-suppression of the chalcone synthase A gene in *Petunia*. In particular, the model involves endonucleolytic cleavage of paired RNA molecules of complementary sequences of aberrant RNA from the *chsA* 3' end and the 3'

untranslated region (see abstract and Fig 7). The complementary RNA regions of this model are however on separate RNA molecules (see Figure 7) and accordingly do not represent an artificial hairpin RNA. To the extent the Examiner considers the molecule represented in Figure 5, page 850 an artificial hairpin RNA within the scope of the claim terms, Applicants respectfully traverse. Although Figure 5 represents arguably an RNA molecule comprising complementary RNA regions which can basepair, this molecule cannot be considered an artificial hairpin RNA, because this is contrary to the definition provided in the specification on page 22. The RNA molecule of Fig 5 is naturally occurring in nature as the sense and antisense regions are occurring naturally simultaneously in one RNA molecule. Furthermore, the Examiner will note that there are no perfectly base-paired RNA regions of at least 10 nucleotides in length, let alone of at least 20 nucleotides in length as recited in the amended claims. Furthermore, the Metzlaff publication is entirely silent on the presence of an intron, particularly an intron which is heterologous to the sense sequence, in the transcribed region of the chimeric genes recited in the claims.

Thus, Metzlafl fails to disclose all the elements of the claimed invention either explicitly or inherently. Withdrawal of the rejection is respectfully requested.

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §102(b) as being anticipated by Stam et al. To the extent the rejection might still be applied to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner alleges that Stam et al. teach plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing

between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense sequence includes at least 10 consecutive nucleotides having 100% sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence. The Examiner particularly points to the bridging paragraph on pp 3-4; figure 1 on page 4 and figure 3 on page 9.

Stam et al. review gene silencing in plants, with a particular emphasis on the observation that T-DNA insertion of the silencing transgenes may result in duplicated T-DNA insertions which may be in direct or inverted repeat orientation (bridging paragraph on pp 3-4). This configuration of the silencing transgenes may either facilitate DNA-DNA pairing, which in the case of the inverted repeat orientation would result in the formation of a cruciform on the DNA-level (page 8, 2nd column, lines 13-14 from the bottom), or may lead to aberrant RNA formation triggering (page 8, 2nd column, lines 11-12). However, as applicants explained during the above mentioned interview it will be clear, that even though hairpins may be formed at the DNA level, there is no disclosure in Stam et al. of the formation of an artificial hairpin RNA molecule as currently claimed.

Finally, the Stam et al. publication is entirely silent on the presence of an intron, particularly an intron which is heterologous to the sense sequence, in the transcribed region of the chimeric genes recited in the claims

Thus, Stam et al. does not teach every element of the claimed invention either explicitly or inherently. Therefore, withdrawal of the rejection is respectfully requested.

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §102(e) as being anticipated by Fire et al. To the extent the rejection might still be applied to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner alleges that Fire et al. teaches plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense sequence includes at least 10 consecutive nucleotides having 100% sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence. The Examiner particularly points to the abstract; column 4, lines 41-61, column 6, line 32 to column 9, line 48; column 12 lines 46-column 13, line 8; claims 1-12 and 21.

The disclosure of Fire et al. is focused on the use of separate RNA strands capable of forming a double stranded RNA structure. Only in column 4, lines 43-45 of Fire et al. is a single allusion made to the possibility of forming a double-stranded RNA structure by a single self-complementary RNA strand. However, a single self-complementary RNA is not to be equated with a artificial hairpin structure comprising a double stranded RNA stem connected by a single stranded RNA loop as recited in claim 39. a double stranded RNA structure formed by “a self-complementary RNA molecule,” is not a clear and unambiguous disclosure of an artificial hairpin structure, and particularly not of an artificial hairpin structure wherein the sense and antisense sequences of the artificial hairpin structure are not naturally occurring in one RNA molecule, or the sense and antisense sequences are separated

by a spacer region which is heterologous with respect to the target gene. Rather, the term “self-complementary RNA molecule” is an indistinct generalization of a genus of potential structures including many other structures such as e.g. a hammerhead structure. It is well established law that disclosure of a broad genus does not anticipate the specific species of that genus. Accordingly, Applicant submit that Fire et al. do not disclose all essential features of the currently claimed methods and therefore do not anticipate the current claims under 35 U.S.C. 102(e).

Furthermore, Fire et al. is totally silent about the presence of an intron in the chimeric DNA molecules described therein. Although some of the passages cited by the Examiner mention the word intron, such citation is in an entirely different context. For example, at column 5, lines 40-46 it is merely indicated that the targeted genes contain exons and introns, while in column 17, lines 20-25, it is mentioned that dsRNA segments corresponding to a variety of intron [...] sequences did not produce detectable inhibition. This hardly amounts to a teaching or even a suggestion to include an intron into chimeric genes encoding dsRNA as currently claimed.

Applicant would also like to draw the current Examiner's attention to the acknowledgement of record by the then responsible Examiner in the conclusion of the Office Action of April 9, 2003 (page 7) that: “US Patent No 6506559 (Fire et al) is considered to be pertinent to Applicant's disclosure because it discloses methods of inhibiting the expression of a target gene using a dsRNA molecule, including an RNA molecule expressed from a DNA vector, however, Fire et al. does not teach these methods wherein the DNA vector comprises a heterologous intron, nor is there any suggestion in the prior art to include such an intron in the DNA vectors expressing a dsRNA of Fire et al.”(emphasis added)

Furthermore in order to remove Fire et al. as an issue, the Examiner's attention is also drawn to the accompanying declaration (Attached as Exhibit B) by the inventors under 37 C.F.R. § 1.131 wherein the inventors declare that embodiments of the presently claimed invention were actually reduced to practice, prior to December 23, 1997 filing date of U.S. provisional application No. 60/068,562 for which benefit is claimed by U.S. Patent 6, 506, 559 ("Fire").

In particular, the inventors declare and demonstrate that prior to December 23, 1997 they successfully constructed, in the CSIRO Plant Industry laboratories in Canberra, Australia, a chimeric DNA construct molecule comprising, in order: a) a promoter(*CaMV35S*), operative in a plant cell (which is a eukaryotic cell); b) a DNA region, which when transcribed, yields an RNA molecule with at least one RNA region with a nucleotide sequence comprising i) a sense nucleotide sequence including at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) having 100% sequence identity with at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) of the nucleotide sequence of the nucleic acid of interest (*0.75 kb PVY region in sense orientation- the nucleic acid of interest was comprised in the genome of an infecting RNA virus in this embodiment*); and ii) an antisense nucleotide sequence including at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) having 100% sequence identity with the complement of the at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) of the sense nucleotide sequence (*0.75 kb PVY region in antisense orientation*); wherein the RNA is capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base-pairing between the regions with sense and antisense nucleotide sequence, and wherein the DNA region further comprises an intron (*intron 2*) (which is a heterologous intron with respect to the sense and antisense PVY sequences); and

c) a DNA region involved in transcription termination and polyadenylation (*3' ocs region*).

See, DECLARATION OF INVENTOR at paragraphs 15-17.

The inventors further declare and demonstrate that prior to December 23, 1997 they successfully constructed, in the CSIRO Plant Industry laboratories in Canberra, Australia, a chimeric DNA molecule (*pMBW233/239 series*) comprising in order, a promoter operative in the plant cell (*Ubi-P*); a DNA region, which when transcribed, yields an RNA molecule with at least one RNA region with a nucleotide sequence comprising a sense nucleotide sequence including at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) having 100 % sequence identity with at least 20 (and also at least 50 or 100 nucleotides) consecutive nucleotides of the nucleotide sequence of a nucleic acid of interest (*Gusd in sense orientation*) in a eukaryotic cell; and an antisense nucleotide sequence including at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) having 100% sequence identity with the complement of the at least 20 consecutive nucleotides (and also at least 50 or 100 nucleotides) of the sense nucleotide sequence (*Gus5' in antisense orientation*); wherein the RNA is capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base-pairing between the regions with sense and antisense nucleotide sequence wherein the DNA region further comprises an intron (*Ubi-I intron*) (which is heterologous to the sense GUS sequence); and a DNA region involved in transcription termination and polyadenylation (*tml'*). See, DECLARATION OF INVENTOR at paragraph 38.

The declaration also demonstrates the successful use of such a chimeric gene in a method for reducing the phenotypic expression of a nucleic acid of interest which is normally capable of being expressed (**GUS gene**) in a eukaryotic cell (a plant cell, *rice*) comprising the

step of introducing into the eukaryotic cell (plant cell) a chimeric DNA (*pMBW233/239 series*) as currently claimed. See, DECLARATION OF INVENTOR at paragraph 39.

The declaration proves that the inventors actually reduced the present invention to practice prior to the earliest possible effective filing date of Fire et al. Therefore, the reference is not prior art reference against the current claims of the application. For at least the foregoing reasons, withdrawal of the rejection is appropriate and is respectfully requested.

New rejections under 35 U.S.C. §103

Claims 22, 26, 42, 43, 54, 56, 58, 63-69, 95-97, 100-103, 106-108 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fire et al in view of Brown et al, Lusky et al. and Schiedner et al, the combination in view of Barachcini et al. To the extent the rejection might still be applied to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner has alleged that Fire et al. (USPN 6,506,559) teaches plant cells, plant and their seeds comprising a nucleic acid comprising a first and second DNA sequence which expresses in the plant cell a chimeric DNA comprising a promoter, operatively linked to a DNA region which, when transcribed, yields an RNA molecule capable of forming a hairpin comprising two annealing RNA sequences which comprise a sense sequence sharing homology with consecutive nucleotides of a target nucleic acid of interest in the plant, and which further comprises a second, annealing RNA sequence comprising antisense sharing homology with the consecutive nucleotides of the sense strand that targets the nucleic acid of interest, and which chimeric DNA further comprises an intron sequence, and which chimeric DNA further comprises operably linked transcription termination and polyadenylation sequences.

The Examiner has alleged that the sole differences between the claimed plant cells, plant and seeds of the current invention and the disclosure by Fire et al. is that Fire et al. do not teach the targeting region of the chimeric construct to span between 10 and 50 consecutive nucleobases. To remedy this deficiency of the primary reference, the Examiner points to secondary documents by Brown et al. (US patent 5,859,347), Lusky et al. (US patent 6,350,575), Schnieder et al and Baracchini et al. More specifically, the Brown et al. document is cited for its teaching of plant cells transformed with chimeric nucleic acid expression constructs expressing desired DNA sequences, which expression constructs include operably linked promoters and further comprising heterologous introns, which introns enhance expression of the desired nucleic acid sequences in the expression construct. Lusky et al. is also cited for its teaching of expression constructs comprising antisense RNA and further comprising an intron as well as other expression elements including translation termination and polyadenylation signals. Schnieder et al. teach expression vectors comprising intronic sequences for enhancing vector stability. Finally, Baracchini et al. is cited for its teaching of the ability to target a gene of interest with a complementary sequence comprising at least 10 nucleobases.

Applicants respectfully disagree with the Examiner's analysis of the teaching of Fire et al., and the secondary references as elaborated extensively in the Reply filed September 12, 2005 and the reply filed May 10, 2006. Moreover, the differences between Fire et al. and the presently claimed invention are greater than has been alleged by the Examiner for the reasons set forth above.

However, in view of the accompanying declaration by inventor under 37 C.F.R. § 1.131 wherein the inventors declare that embodiments of the presently claimed invention were made, i.e. actually reduced to practice, prior to December 23, 1997 filing date of U.S.

provisional application No. 60/068,562 for which benefit is claimed by U.S. Patent 6, 506,559, the primary reference is no longer applicable as a proper prior art reference. Since none of the secondary references even hint at the possibility to target expression a gene of interest with a chimeric DNA encoding an artificial hairpin RNA as currently claimed, the remaining references cannot possibly support a prima facie case of obviousness.

Accordingly, withdrawal of the rejection is appropriate and respectfully requested.

Request for rejoinder of process claims 1-10,12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104, 105, 111 and 123.

The withdrawn process claims 1-10,12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104, 105, 111 and 123 include all the limitations of the product claims under consideration.

Accordingly, Applicant requests that the restriction between withdrawn process claims and the product claims be withdrawn in accordance with the Manual of Patent Examination Procedure § 806.05(h).

Respectfully submitted,

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